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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,705	10/03/2006	Joseph Hermes Kaal	28091/220	3518

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EXAMINER	
RANADE, DIVA	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,705	KAAL ET AL.	
	Examiner	Art Unit	
	DIVA RANADE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: '41' See Page 9 line 24. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: '54' See Fig 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

5. Claim 16 recites the limitation "respective steps" in said first plunger member. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 17 recites the limitation "respective ledges" in said first plunger member. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims that following retraction of the first plunger member, the needle mount and needle, said second plunger member and said seal remain at a needle end the barrel thereby preventing refilling and re-use of the syringe. The needle mount is connected to the proximal end of the needle and therefore all elements cannot remain at a needle end the barrel. Examiner will interpret claim as meaning that no element can move beyond the end of the barrel. Further "a needle end the barrel," needs to be reworded.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4-8, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,211,628 to Marshall.

a. Claim 1: Marshall shows a plunger for a retractable syringe (10) having a spring (54) and a needle mount (28), said plunger comprising a first plunger member (43) and a second plunger member (66) that are capable of being releasably engageable to co-operatively maintain said spring in an initial compressed state, arranged so that disengagement of said first plunger member and said second plunger member can facilitate decompression of said spring from the initial compressed state when required to force retraction of said first plunger member and said needle mount when engaged therewith, following depression of said plunger to deliver fluid contents of said syringe.

b. Claim 2, 8: Marshall shows that the first plunger member and the second plunger member are capable of being releasably engageable by a bayonet coupling but are instead coupled by lip (44).

c. Claim 4, 10: Marshall shows that the first plunger member comprises a needle mount engagement device (64).

d. Claim 5, 11: Marshall shows that the needle mount engagement device comprises two barbed arms (64).

e. Claim 6, 13: Marshal shows wherein the second plunger member comprises a seal (62 and see Column 3 lines 2-5)) mounted thereto.

f. Claim 7: Marshall shows a retractable syringe (10) comprising a plunger (38), a barrel (12), a spring (54) and a needle mount (28), said plunger comprising a first plunger member (43) and a second plunger member (66) that are capable of being releasably engaged to co-operatively maintain said spring in

an initial compressed state and are disengageable to facilitate decompression of said spring to force retraction of said first plunger member and said needle mount, when engaged therewith, following depression of said plunger to deliver fluid contents of said syringe.

g. Claim 12: Marshall shows needle mount comprises recesses (see recesses inside lips 36 in Fig 4) that are respectively engageable by the barbed arms.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,211,628 to Marshall.

h. Claim 3, 9: Marshall shows wherein said first plunger member (38) and said second plunger member (66) can be disengaged after needle mount is mounted by needle mount engaging means but does not show disengagement by rotation of the first plunger member relative to the second plunger member. However, as stated in claim 2 above the means of coupling chosen here is a lip but had it been a bayonet coupler, which Marshall is capable of having, disengagement could be achieved by rotation. Therefore, it would be obvious to one skilled in the art during the tie of the invention to use a more secure method

of coupling the plunger members so that the plunger members would need to be rotatably disengaged rather than automatically disengaged upon attachment to needle mount in order to allow for a greater degree of efficacy in disengagement and to reduce instances of malfunction.

11. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,211,628 to Marshall in view of U.S. Publication 2003/0158525 to Thorley et al.

i. Claims 14 and 15: Marshall lacks a collar mounted to the barrel. Instead Marshall employs the locking mechanism of fitting projection (61) into slot (46). Thorley shows a collar mounted onto the barrel. The collar of Thorley comprises one or more projections capable of co-operating with one or more abutments of said first plunger member to form a plunger disabling means device that is capable of preventing subsequent depression and/or withdrawal of said first plunger member following retraction of the needle mount as in claim 15 (See [0016]). It would be obvious to one skilled in the art during the time of the invention to add the collar of Thorley to the barrel of Marshall in order to provide a more secure locking means to Marshall.

j. Claim 16: Marshall lacks a collar mounted to the barrel. Instead Marshall employs the locking mechanism of fitting projection (61) into slot (46). Thorley shows a collar mounted onto the barrel wherein the one or more projections comprise a pawl (422A) but lack two pawls that are engageable with a respective step (475) on said first plunger member to co-operably prevent subsequent

depression said first plunger member following retraction of the needle mount and thereby prevent syringe re-use. It would be obvious to one skilled in the art during the time of the invention to add more pawls to increase efficacy of locking mechanism.

k. Claim 17: Marshall lacks a collar mounted to the barrel. Instead Marshall employs the locking mechanism of fitting projection (61) into slot (46). Thorley shows a collar mounted onto the barrel wherein the one or more projections comprise a rib (422B) but lacks two ribs that are engageable with a respective ledge (474) on said first plunger member to co-operably prevent subsequent withdrawal of said first plunger member following retraction of the needle mount and thereby prevent syringe re-use. It would be obvious to one skilled in the art during the time of the invention to add more ribs to increase efficacy of locking mechanism or to guide plunger through the barrel.

l. Claim 18: Marshall shows a retractable syringe (10) comprising:

[[(i)]] a barrel (12);

[[(ii)]] but lacks a collar mounted to the barrel and comprising two ribs and two pawls; (Modify Marshall with Thorley, See above)

[[(iii)]] a retraction spring (54);

[[(iv)]] a needle mount (28) located at a needle end of the barrel (22); and

[[(v)]] a plunger (38) operably located in said barrel and engageable with said needle mount, said plunger comprising:

[[(a)]] a first plunger member (43) (modified by Thorley See claim 16 and 17

rejection) having two steps and two ledges; and

[[(b)]] a second plunger member (66) and a seal (62) mounted thereto;

wherein the first plunger member and the second plunger member are releasably coupled to co-operatively maintain said spring in an initial compressed state and can subsequently be rotatably uncoupled to facilitate decompression of said spring to force retraction of said first plunger member and said needle mount when engaged therewith following depression of said plunger to deliver fluid contents of said syringe (See rejection above for Claims 3 and 9) and wherein said two pawls are engageable with respective steps on said first plunger member to co-operably prevent subsequent depression said first plunger member and said two ribs are engageable with respective ledges on said first plunger member to co-operably prevent subsequent withdrawal of said first plunger member following retraction of the needle mount and needle (See rejection for claims 16 and 17 above).

m. Claim 19: Marshall shows that the syringe is arranged so that following retraction of the first plunger member (43), the needle mount (28) and needle (32), said second plunger member (66) and said seal (61) remain at a needle end the barrel thereby preventing refilling and re-use of the syringe (See Fig 3).

12. Claims 20-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,211,628 to Marshall.

n. Based on Marshall in claims 1-13 modified by Thorley for claims 14-19 it would be obvious to one skilled in the art to use the method described in claim

20-35 in order to assemble the syringe in a functional manner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. R./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763